Edoxaban prescription patterns in Europe: a retrospective drug utilisation chart review study (ETNA-DUS)

First published: 04/01/2017

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Study Ongoing

Administrative details

EU PAS number

EUPAS17062

Study ID

26641

DARWIN EU® study

No

Study countries

- Belgium
- Germany
- Italy
- Portugal

Spain

Switzerland

United Kingdom

Study description

Edoxaban (E.) is an orally administered anticoagulant that inhibits coagulation factor Xa. It is currently approved for use in adult patients with Non-Valvular Atrial Fibrillation (NVAF) with one or more risk factors, such as Congestive Heart Failure (CHF), hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or Transient Ischemic Attack (TIA) for prevention of stroke and systemic embolism. In addition, E. is approved for the treatment of Venous Thromboembolism (VTE) including Deep Vein Thrombosis (DVT) and/or Pulmonary Embolism (PE), and prevention of recurrent VTE in adults.Clinical development programs have been undertaken to support marketing authorization submissions for E. in those indications. However, as it is the case with any medicinal product, real-life use of E. may differ from or extend beyond the patient population that has been studied in the phase 3 program or is included under the approved indication. One of the concerns in real-world use of medicinal practices is the off-label use. Daiichi Sankyo (DS) addressed this concern in the Risk Management Plan in order to anticipate necessary risk minimization activities. The potential off-label use of E. in unapproved indications was considered low, because of the availability of approved, indicated and well-established treatment alternatives. In order to further optimise the correct use of the medicinal product by the physician, DS is implementing additional risk minimisation activities such as a prescriber guide as part of the educational programs for prescribers (information about approved indications, E. eligible patients, dosing and safety concerns management) and patient alert card.The Drug Utilisation Study (DUS) aims to gain insight on how this new European medicinal product is going to be used in real practice.

Study status

Ongoing

Research institutions and networks

Institutions

Barnet General Hospital

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Institution

PD Dr. Ameet Bakhai

Contact details

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Primary lead investigator

Diana Wolpert

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 08/08/2016

Study start date
Actual: 12/12/2016

Date of interim report, if expected
Planned: 29/09/2017

Actual: 27/09/2017

Date of final study report
Planned: 30/09/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Daiichi Sankyo Europe GmbH

Study protocol

ETNA-DUS_Observational Plan_v 6.0_08-Jun-17.pdf (1005.01 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

The aim of this Drug Utilisation Study (DUS) is to provide real-world data related to the current prescription patterns of edoxaban. Study objectives are as follows:• To characterize users of edoxaban,• To evaluate the pattern of use of edoxaban,• To evaluate the effectiveness of the edoxaban Educational Material as a tool for risk minimization.

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

EDOXABAN TOSYLATE MONOHYDRATE

Medical condition to be studied

Atrial fibrillation

Embolism venous

Population studied

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

1.200

Study design details

Data analysis plan

Details of the data analysis strategy will be fully described in a Statistical Analysis Plan (SAP). Briefly, descriptive statistics will be used to characterize prescriber and patient information. Summary statistics for continuous variables

will include the number of observations, along with measures of location (means, medians) and variation (e.g. standard deviation, range). Categorical data will include counts and percentages. The 95% CIs will be reported where appropriate. Per country analyses will be performed where reasonable, as some subgroups might be too small to be looked at per country. The data may also be evaluated and presented for other meaningful subgroups of patients (e.g. by patients for which there is missing information).

Documents

Study report

ETNA-DUS_Interim Report_27-Sep-17.pdf (6.68 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prescription event monitoring

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No